UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

FWK HOLDINGS, LLC, on behalf of itself and all those similarly situated, *Plaintiff,* v. ALLERGAN, INC., *Defendant.*	Civil Action No. **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT & JURY TRIAL DEMAND

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I. INTRODUCTION

1. This civil antitrust action arises from Allergan's scheme to unlawfully prolong its monopoly in the market for prescription cyclosporine emulsion sales in the United States. This complaint seeks damages on behalf of the plaintiff, FWK Holdings, LLC, and a proposed class of purchasers that bought Restasis directly from the defendant, Allergan, Inc. at supracompetitive prices.

2. Federal law rewards inventors with a fixed period of patent protection for their novel and non-obvious inventions. But once this legally-sanctioned monopoly ends, the law prohibits the patent holder from trying to unlawfully prolong its monopoly. A patent holder may not obtain additional, later-expiring, patents by misrepresenting facts to the Patent and Trademark Office ("PTO"). It may not sue competitors for alleged infringement of such bogus patents. It may not file baseless petitions with the FDA. And it may not prolong its monopoly by transferring ownership of the invalid patents to a sovereign Native American tribe in order to destroy jurisdiction over those patents. Each of these actions, independently and collectively, delays generic competition and violates the antitrust laws and Allergan engaged in each of these illegal acts in order to illegally extend its Restasis monopoly.

3. Allergan made about $3.3 billion from selling Restasis in the U.S. for eleven-and-a-half years, while it was protected by the U.S. Patent No. 5, 474, 979 (the "979 Patent" or "Ding I patent," which issued in 1995. But Allergan was not satisfied with its legitimate blockbuster earnings; it wanted more. So Allergan devised and carried out a multifaceted, anti-competitive scheme to keep its would-be generic competitors off the market for as long as possible. The scheme had the following elements.

4. *Fraud on the Patent Trademark Office.* In the wake of the PTO repeatedly rejecting its efforts to obtain new patents covering Restasis, Allergan resorted to falsely claiming

that clinical data showed unexpected effectiveness and surprising test results. The examiner stated that he issued the second wife Restasis patents (the "second wife patents") because of the unexpected increase in relative efficacy. The second wave patents are both obvious in light of prior art and invalid/unenforceable due to Allergan's fraud.

5. *Wrongful Orange Book listing.* Allergan listed the second wave patents in the Food and Administration's ("FDA's") Orange Book. This required would-be generic competitors to either wait to launch generic version of Restasis until patent expiry or challenge the validity of the patents by making a so-called "paragraph IV" certification to Allergan. Listing the patents triggers a generic company's responsibility to tell Allergan if it intends to launch before the expiration of the second wave patents.

6. *Wrongful FDA petitions.* Immediately, after improperly listing in the Orange Book the second wave patents, Allergan submitted a series of petitions and comments to the FDA that asked the FDA not to approve generic versions of Restasis unless Generic competitors satisfied expensive, time-consuming and unnecessary condition that the FDA does not typically impose on drug makers looking to market generic versions of brand-name drugs whose safety and efficacy has already been proven. No reasonable pharmaceutical company in Allergan's position would expect the FDA to grant the relief that Allergan sought, and the FDA denied its various petitions (granting only two requests that asked FDA to do what it would have done anyway).

7. *Wrongful patent enforcement.* Upon receiving paragraph IV certifications from potential generic competitors Actavis (formerly known as Watson, in 2014), and Apotex, Akorn, Teva, and Mylan (all in 2015), Allergan sued each for patent infringement in this district. It did this despite knowing that the data the PTO had relied on in issuing the patents was neither new

nor unexpected. Each generic company responded that Allergan's second wave patents were invalid. No reasonable pharmaceutical manufacturer in Allergan's position would realistically expect to win the litigation. But simply by filing suits, Allergan guaranteed that its competitors would not get to market for two-and-a-half years.

8. *Conspiracy to monopolize and contract in restraint of trade.* In December 2016, the Patent and Trademark Appellate Board ("PTAB") held, in response to multiple requests for *inter partes* review of the second wave patents, that there was a reasonable likelihood that the second wave patents would be invalidated after the PTAB concluded its review. Faced with the reality that the PTAB would invalidate its patents, Allergan entered into a contract in restraint of trade with the Saint Regis Mohawk Tribe (the "Tribe") to wrongfully perpetuate Allergan's monopoly by transferring ownership of the second wife patents to the Tribe, and then petitioning the PTAB to dismiss its review for lack of jurisdiction (based on the Tribe's sovereign immunity).

9. *Purchasers were injured.* As a result of Allergan's anticompetitive scheme, Allergan earned, to date, an extra $3.9 billion in monopolistic Restasis sales since May 17, 2014 – at direct purchasers' expense. In the absence of Allergan's unlawful actions, generic Restasis would have been available by May 17, 2014 and direct purchasers would have purchased the less expensive generic. FWK Holdings, LLC and the proposed class have paid hundreds of millions of dollars in overcharges as a result of Allergan's anticompetitive scheme.

II. PARTIES

10. Plaintiff FWK Holdings, LLC ("FWK" or the "Plaintiff") is a limited liability company organized under the laws of the State of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Co. During the relevant period, Frank W. Kerr Co. purchased Restasis directly from Allergan at

supra-competitive prices as a result of Allergan's scheme.

11. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located in Irvine, California. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the Restasis trademark. Allergan also was the applicant for and holder of each of the six second wave patents which Allergan has claimed cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014), U.S. Patent No. 8,648,048 (dated Feb. 11, 2014), U.S. Patent No. 8,685,930 (dated Apr. 1, 2014), and US 9,248,191 (dated Feb. 2, 2016). As of September 8, 2017, Allergan purports to have transferred its ownership interests in the second wave patents to the Tribe.

12. All of the actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and/or with Allergan's actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

13. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2 and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, interest, costs of suit and attorneys' fees for the injuries sustained by FWK and other Class members resulting from Allergan's unlawful foreclosure of generic cyclosporine sales in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1332(a), and 15 U.S.C. § 15.

14. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a), 22, and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period (defined below), Allergan resided,

transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this district. Significantly, during the Class Period, Allergan has maintained and continues to maintain significant offices and operations in Texas. During the Class Period, Allergan operated a facility in Texas where it manufactured and distributed numerous pharmaceutical products, including Restasis, whose nationwide distribution is coordinated from a site in Texas. In addition, venue is proper in this district because Allergan has availed itself to this judicial district by purposefully selecting this venue to pursue the sham patent-infringement lawsuits against generic competitors, which litigation was part of the multifaceted anti-competitive scheme alleged in this Complaint. *See* Allergan, Inc.'s Complaint for the Patent Infringement, ECF No. 1, in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action 2:15-cv-1445 (E.D. Tex.).

15. Allergan's conduct, as described in this complaint, was within the flow of, was intended to have a substantial effect on, and did have a substantial effect on, the interstate commerce of the United States, including in this district.

16. During the Class Period, Allergan manufactured, sold, and shipped Restasis in a continuous and uninterrupted flow of interstate commerce, which included sales of Restasis in this district, advertisement of Restasis in media in this district, monitoring prescriptions of Restasis by prescribers within this district, and employment of product detailers in this district, who as agents of Allergan marketed Restasis to prescribers in this district. Allergan's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

17. This Court has personal jurisdiction over Allergan. Allergan, throughout the

United States and including in this district, has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY BACKGROUND

A. Economics of Generic Substitution

18. Brand drug companies can, and do, obtain valid patents that cover new prescription drug products.

19. Once the lawful periods of patent exclusivity expire on branded products, would-be competitors can seek FDA approval to sell generic versions of the brand, allowing those companies to manufacture generic products that are just as safe and effective, but far less expensive than the brand.

20. Brand companies are required to provide the FDA information about patents claiming their particular drug product. The FDA must rely, completely, on the information provided by the brand and list those patents publicly, so that would be generic competitors understand the scope of the brand's ostensible patent protection.

21. Branded drug companies have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture. But it is a limited period, after which would-be competitors may enter the market with lower-cost substitutes.

22. As a further guard against error in the patent prosecution process that may result in improvidently issued patents, Congress recently established an "inter partes review" process that empowers the PTAB to review the validity of a previously issued patent, and, if it determines that the challenger "has a reasonable likelihood of prevailing on at least one of the challenged claims," conduct a trial on the invalidation issues in which the patent holder is the

defendant.

23. From this framework, some basic rules emerge. First, brand drug companies may pursue only valid patents, with candor and forthrightness in dealing with the PTO. Second, brand drug companies cannot provide false or misleading patent or other drug information to the FDA and use that information to delay entry of less expensive generic medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Third, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success on the merits; the mere filing of such a lawsuit delays legitimate efforts to gain market entry. Fourth, federal policy favors prompt invalidation of improvidently issued patents; patent holders cannot knowingly use invalid patents as anticompetitive weapons and evade the consequences.

24. Allergan broke all of these basic rules.

25. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

26. Since the passage of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, (the "FDCA") every state has adopted substitution laws that either require or

permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

27. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

28. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Allergan, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

1. Prices plummet when additional AB-rated generics enter the market.

29. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

30. Soon after generic competition enters the market, the vast majority of the sales formerly enjoyed by the brand shift to the generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

31. There is a predictable pattern to the way brand drug companies develop their patent portfolios. The first group of patents in the brand drug company's portfolio for the drug

may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

32. After filing applications for the original patents, the company continues its research and development efforts in the hopes of developing a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow on patents that can be obtained. New patents can be obtained for features of the drugs only if the brand drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. And often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the brand drug company must show non-obvious distinctions.

33. Patents present, at minimum, obstacles for would be generic competitors to design around. Some patents broadly cover a drug's active ingredient and if valid and enforceable may prove impossible to design around while meeting the FDA's criteria for equivalent generics. While generic versions of the brand product may be able to obtain FDA approval and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of trying to prevent competitors from entering the market.

34. Therefore, a typical patent portfolio for a brand drug has its most significant

patents issuing first; over time, the later issued patents generally become increasingly narrow and more difficult to obtain. Even if the narrower coverage is obtained, these later issuing parents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would be generics, thus preventing the brand from satisfying its burden of proving infringement to keep generics out of the market.

2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties designed to protect the public interest in the PTO's issuance of valid and lawfully obtained patents.

35. Because patents often enable a branded-product manufacturer to exclude competition and charge supracompetitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

36. Patent prosecutions are non-adversarial. Thus, in order to help assure that the "public interest is best served" though the PTO's issuance of patents that are valid and lawfully obtained, patent applications are subject to various special oaths and duties. Among these various special oaths and duties is the duty of disclosure, candor, and good faith, which requires the applicant to disclose to the PTO of "all information known . . . to be material to patentability" including with respect to prior art. *See* 37 C.F.R. § 1.56. And this duty extends not only to each and every named inventor on the patent application but to each and every "attorney or agent who prepares or prosecutes the application" as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id*. § 1.56(c). Where fraud on the PTO "was practiced or attempted" or the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct" no patent should be granted. *Id*. § 1.56(a).

B. New Drug Applications (NDAs) and Patent Listings in the FDA's Orange Book

37. Under the FDCA drug companies who wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include submission of specific

data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

38. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA then publishes a list of those patents in the publicly available "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

39. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the resources or authority to verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book-listed patents.

C. Abbreviated New Drug Applications (ANDAs), Orange Book-Related Generic Manufacturer Certifications, and Related Litigation

40. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the FDA that may rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the blood

stream at a similar rate over a similar period of time are expected to be equally safe and effective.

1. Hatch-Waxman provides for an automatic 30-month stay of FDA ANDA approvals to resolve legitimate patent infringement claims.

41. The Hatch-Waxman Amendments created a procedural mechanism to resolve patent disputes between brand and generic manufacturers before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Amendments permitted a brand manufacturer to sue a generic for patent infringement even if their products had not launched yet.

42. Once one or more patents are listed in the Orange Book, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any of those patents in order to obtain FDA approval of that ANDA. A generic manufacturer can make one of four certifications:

i. That no patent for the brand name drug has been filed with the FDA;

ii. That the patent for the brand name drug has expired;

iii. That the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

iv. That the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product.

43. If a generic manufacturer files a paragraph IV certification, a brand name manufacturer can sue the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of

receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

44. The brand manufacturer could file patent infringement claims more than 45 days after receiving the paragraph IV certification, but doing so would not trigger the automatic 30-month stay of FDA approval.

2. Hatch-Waxman incentivizes generics to challenge questionable patents before launch by awarding 180 days of exclusivity to the first paragraph IV-certified ANDA filer.

45. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a paragraph IV certification receives 180 days of market exclusivity. This means that other, secondary ANDA-filers will not be able to launch their own generic products for at least six months after the first generic—known as the "first-filer"—launches its product.

46. If the only versions of a drug on the market are the brand and the first filer's product, then the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first filer's product may compete only with the brand, and because the branded company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition that arises when additional generic competitors enter the market.

D. The Citizen Petition Process

47. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

48. Citizen petitions provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product before, or after, its market entry.

49. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

50. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because the FDA must research the petition's subject, examine scientific, medical, legal and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources.

51. The FDA's longtime practice – well-known in the pharmaceutical industry – had been to withhold ANDA approval until after its consideration of, and response to, a citizen petition regarding that ANDA was complete. The former director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research ("CDER") acknowledged that it was "very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

52. For more than a decade, a number of brand-name pharmaceutical manufacturers have abused the citizen petition process, using it as a tactic to extend their monopolies on their

branded drugs when faced with entry by generic competitors. Citizen petitions by rival companies rarely raise legitimate concerns about the safety or efficacy of generic products, and instead only seek to preserve monopolies after the end of a statutorily-granted patent or FDA exclusively period. The timing of these tactical filings is important: companies frequently file these citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, before. This results in delay of approval (tentative or final) of a pending ANDA for several months (or more) while the FDA evaluates the merits of the citizen petition.

53. The resulting delay of generic competition can be lucrative for an incumbent brand-name manufacturer facing impending competition from an AB-rated generic. The cost of filing a baseless sham citizen petition pales in comparison to the value of securing an additional period of monopoly profits.

54. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last 15 years, as brand-name companies have sought to compensate for dwindling new product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand-name manufacturer received notice of the ANDA filing, and have had the effect of delaying the approval of the generic product while the FDA evaluates the citizen petition.

55. The FDA has long acknowledged citizen petition abuse, stating as far back as 2005 that it had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try and delay the approval simply by compelling the agency to take the

time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

56. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. 355(q) (the "FDAAA"), which added new section 505(q) to the FDCA providing that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The FDAAA does not, however, provide the FDA with additional resources that might allow it to more promptly respond to citizen petitions – meaning that a brand-name drug maker can still use the citizen petition process to delay generic approval while the FDA considers whether the company's citizen petition implicates issues of public health, regardless of whether the petition has any real merit.

57. Years after the enactment of the FDAAA, the FDA continues to have serious concerns about the abuse of the citizen petition process for anticompetitive purposes, noting in a 2012 report to Congress that "based on the petitions that FDA has seen to date . . . the agency is concerned that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products." Indeed, recent studies have found that many citizen petitions from brand-name drug manufacturers "appear to be last-ditch efforts to hold off generic competition," and that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, which are the type most often used – like Allergan did here – to delay generic entry.[1]

[1] Feldman *et al*., *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 70 (2017); Carrier & Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 332-333, Table 4 (2016).

E. Proceedings Before the Patent Trial and Appeal Board

58. In 2011, Congress passed the Leahy-Smith America Invents Act to address a widely-held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy. A centerpiece of the Act was the creation of new "inter partes review" (IPR) proceedings, by which members of the public could challenge improperly-issued patents and have them eliminated much more quickly and inexpensively than through expensive and time-consuming patent litigation. IPR proceedings also bore the promise of a review by technically-educated members of the PTAB who are deeply familiar with the sciences at issue in any particular proceeding.

59. The Act allows the PTAB to review existing patents and extinguish those rights in an adversarial trial process. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to reconsider the PTO's issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art.

60. The PTAB will grant a request for an IPR only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The PTAB must decide the review within one year of the institution date.

61. The PTAB trial proceedings have become an exceedingly effective method of challenging improperly-granted patents—at least 84 percent of patents reaching a final written decision in PTAB validity challenges are adjudicated to have at least one invalid claim, and 69 percent have had *all claims* cancelled as invalid.[2]

[2] Steve Brachmann & Gene Quinn, Are more than 90 percent of patents challenged at the PTAB defective?, June 14, 2017, http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/ (last visited Nov. 1, 2017).

V. FACTUAL ALLEGATIONS

A. The FDA Approves Allergan's Restasis

62. Cyclosporine treats DED, also known as keratoconjunctivitis sicca ("KCS"), a painful and irritating condition involving abnormalities and deficiencies in the tear film of the eye. More severe cases of dry eye can involve or precipitate inflammation with serious potential damage to the ocular surface.

63. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A,[3] an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is used to treat a condition called "dry eye" — essentially, the failure to produce tears in the normal fashion. Restasis is one of the most widely prescribed drugs in the world; last year, in the United States alone sales of Restasis were nearly $1.5 billion.

64. In 1993, Allergan licensed from Sandoz, Inc., the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent No. 4,839,342 to Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle, in this case topical administration. The Kaswan patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

65. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine),

[3] Cyclosporin A is sometimes spelled "cyclosporine" to distinguish it from other cyclosporins, such as cyclosporins B, C, and D. See U.S. Pat. No. 4,839,342, col. 3, ll. 7-11.

together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "the Ding I patent"), which issued in 1995. The Ding I patent contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. The Ding I patent stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the more preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12. The formulation for Restasis falls within the range of values disclosed and claimed in the Ding I patent.

66. The second patent, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method of alleviating dry eye related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

67. Allergan then began clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (*e.g.*, 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the periodical article Dara Stevenson et al., *Efficacy and Safety of Cyclosporine A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-

severe dry eye disease, and mitigated dry eye disease's effects on vision-related functioning. All tested concentrations were safe and effective in increasing tearing in certain patient groups.

68. Notably, Stevenson concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and the formulations containing greater amounts of cyclosporine—efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson's study suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

69. Phase 3 trials did just that, with the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000). Phase 3 confirmed the results of Phase 2, and found the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over the patient's baseline, suggesting that it was a contributing factor to the formulations' success.

70. Statistically, there was no significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

71. Following the Phase 3 study, Allergan filed a New Drug Application ("NDA") with the FDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The proposed commercial product, which is Restasis, would contain all of the

components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the application in December 2002, authorizing the sale of Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs."[4] Since its launch in 2003, Restasis has been a highly successful product for Allergan.[5]

B. Allergan Prosecutes Serial Patent Application in an Effort to Obtain Additional Patents to Extend the Restasis Monopoly

1. The PTO repeatedly rejects Allergan's serial efforts to obtain additional patents for "new" combinations of castor oil and cyclosporine that were obvious in light of prior art.

72. For over a decade following the FDA's approval of Allergan's Restasis NDA, Allergan filed a variety of patent applications focusing on patenting combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations, with no statistically different outcomes based on the particular combination. Among others, Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and, unsurprisingly, the PTO examiner

[4] The FDA's Medical Review for Restasis does not support Allergan's claim that the results of the Phase 3 studies were unexpected. The FDA did not conduct a pair-wise comparison between the 0.05% cyclosporine formulation and the 0.1% formulation, and it drew no statistical conclusions from the relative performance of the two cyclosporine formulations.

[5] In 2003, particularly in light of the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000), Restasis's success was not surprising. At the time, the prior art taught towards, not away from, using a 0.05% cyclosporine/1.25% castor oil emulsion as a potentially effective treatment for dry eye.

rejected the remaining claims based in part on obviousness in light of the Ding I patent.

73. Allergan then amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis, and, as would be expected, the PTO examiner again rejected the application. Allergan appealed and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but it added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

2. In 2009, Allergan concedes that all its "new" cyclosporine/castor oil combination claims are obvious in light of Ding I

74. In June 2009, Allergan contradicted its earlier patentability claims, and conceded, with respect to both the '857 and '177 applications that the various composition claims were obvious in light of Ding I. Allergan explained, in writing, that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan, in its own words, "concede[d] that in making this selection (0.05% cyclosporine and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." According to Allergan, the composition claims advanced by the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal.

75. After canceling the previous claims on the '857 application, Allergan tried once more to add to it a new claim regarding another composition of cyclosporine and castor oil. As

with all the other composition claims, the PTO examiner rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the '857 application. The '177 application ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

3. Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of new continuation applications, all deriving from the '177 application.

76. Having repeatedly failed to convince the PTO to grant patent protection over various "new" composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, in August 2013, Allergan filed six additional continuation applications deriving, directly or indirectly, from the '177 application. These six additional applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As a federal court invalidating the patents that subsequently issued from these applications later found, "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014." *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455, ECF No. 523 at 20 (E.D. Tex. Oct. 16, 2017) (hereinafter, "Invalidation Decision").

77. In initiating these 2013 applications, Allergan tried to claw back its prior concession that various cyclosporine-castor oil combinations were obvious in light of Ding I, claiming to have new data supporting patentability, based on "unexpected" results showing the claimed Restasis formulation to be particularly effective. The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

78. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists, which according to Allergan, demonstrated that the Restasis formulations reflected in the 2013 applications outperformed other combinations to a "surprising" extent not anticipated by Ding I and other prior art. Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated surprising test results, namely:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . . . Exhibits E and F also illustrate that the claimed formulations also demonstrated a *4-fold* improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a *4-fold* increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

79. On the basis of Allergan's representation of Dr. Schiffman's discovery and the declaration itself, the PTO examiner reversed course. The examiner stated that the Schiffman declaration "is deemed sufficient to overcome the rejection … based on [Ding I] … because …Examiner is persuaded that, unexpectedly, the claimed formulation … demonstrated an 8-fold in increase in relative efficacy…." The Examiner allowed the patents to issue with respect to all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and in 2016 as U.S. Patent No. 9,248,191 ("the '191 patent"). These are the second wave patents at issue here.

4. Allergan's new 2013 data and unexpected results were neither new nor unexpected, and fraudulently induced the PTO to grant the second wave patents.

80. In reality, however, the statements and data reflected in Dr. Schiffman's declaration that Allergan represented to the PTO examiner as presenting new and unexpected results were not new. Instead, Dr. Schiffman's declaration consisted of statements plagiarized from an article published in a well-known medical journal thirteen years earlier, Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article"), and which article had relied on Allergan's very own Restasis Phase 3 clinical trial data that it had recorded in the 1990s. In fact, this was the very publication that publicized Allergan's Phase 3 clinical results.

81. Not only was the "new" 2013 data not new, it did not demonstrate unexpected results. As the federal court which invalidated the Second wave patents recently found, Allergan's:

> presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

Invalidation Decision at 133.

82. In submitting the 2013 continuing applications, Allergan sought new patent protection on substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of prior art. The PTO examiners granted these claims only upon reliance on Allergan's Shiffman Declaration and Allergan's characterizations of "new" data and surprising

results not contemplated by the prior art.

83. Allergan made these representations and characterizations, both by commission and omission, with the intent to deceive the PTO, and such representations and characterizations were material and fraudulently induced the PTO to grant the second wave patents. As a federal court later found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO . . . and the fact that the examiner concluded that unexpected results had been shown . . . the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, *painted a false picture* of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation *created the misleading perception* that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of unexpected results to be entitled to no weight, based as it was on evidence that *did not accurately depict* the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

Id. at 82-83 (emphasis added).

84. Had Allergan made clear to the PTO examiner that the Shiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every other prior application: that the claims presented were all obvious in light of the prior art.

C. Allergan Wrongfully Lists its Invalid second wave patents in the Orange Book, Creating Confusion and Delay in the ANDA Approval Process While Providing a Path to Filing Sham Patent Infringement Suits Against Would-Be Generic Competitors to Further Delay Generic Entry

85. The Second wave patents issued beginning on January 14, 2014, starting with the '111 patent, which Allergan immediately listed in the Orange Book. This listing required any ANDA filer seeking to market generic Restasis to now file a certification as to that "new" patent.

86. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, the Agency had received at least one ANDA for generic Restasis. Up until the listing of the second wave patents, ANDAs may have been filed with paragraph ii and/or iii certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, just months away. Without Allergan's machinations, any paragraph ii and/or iii certified ANDAs would have been unhindered by any patents or citizen petitions, resulting in approval of generic Restasis as early as May 17, 2014 (and in any case, within the class period), and generic competition to Restasis would have created immediate benefits to the Class in the form of lower prices.

87. Instead, all prior ANDA filers now had to amend their ANDAs to include paragraph IV certifications with respect to the '111 patent (and eventually the other second wave patents). Worse, the confusion Allergan created by its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received any prior ANDA certifications likely was different than the order in which the agency received the paragraph IV certifications with respect to the second wave patents, creating various first-filer status uncertainties.

88. The wrongful Orange Book listings had another immediate impact: they effectively required all ANDA applicants to file paragraph IV certifications with respect to the second wave patents, which thereby enabled Allergan to sue for infringement and trigger the automatic stay of any FDA approval of such ANDA for up to 30 months. In contrast, paragraph ii or iii-certified ANDAs are not subject to that automatic 30-month stay of FDA approval.

89. Allergan knew when it listed the second wave patents in the Orange Book that

such patents were invalid but nevertheless would provide Allergan a basis to delay generic competition to Restasis beyond May 2014 and otherwise would create confusion that would further chill the FDA's ANDA approval process.

D. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I

90. Beginning in 2011, and continuing in 2012 and thereafter, numerous pharmaceutical manufacturers— including some of the biggest brand and generic pharmaceutical companies in the world—have submitted ANDAs seeking the FDA's approval to market generic Restasis. Upon information and belief, but for Allergan's misconduct as alleged herein, one or several of these ANDA filers would have received FDA approval and would have been in a position to supply the commercial quantities of generic Restasis necessary to supply the market upon expiration of Ding I as early as May 2014. Other ANDA applicants would have been ready at a later date but still within the relevant period.

91. The long list of generic companies that to date have filed ANDAs seeking to market generic Restasis include Watson, Teva, Mylan, Akorn, Apotex, Innopharma (Pfizer subsidiary), Famy Care, Twi Pharmaceuticals, and Deva Holding. But for the resource-drain, confusion, and administrative delays on FDA and Restasis ANDA filers resulting from Allergan's improper Orange Book listing, citizen petitions, and/or patent suits, some or all of these generic competitors would have been approved and on the market at an earlier period, beginning as early as May 2014—over thirty months after the first ANDA seeking approval for generic Restasis was filed with the FDA—and in any case well before now.

92. The existence of multiple Orange Book-listed patents, multiple citizen petitions concerning complicated generic approvability standards, ongoing patent litigation, and especially the cumulation of the foregoing, can act as a disincentive for generics considering whether and

when to aggressively pursue submission and/or approval of a particular ANDA. The process of contesting even baseless (but complicated) legal or scientific assertions necessarily adds to the time and resources required for the generic approval process, both with respect to the ANDA applicants seeking generic approval and the FDA in reviewing those applications, all of whom must set priorities to allocate limited resources.

93. ANDA filers are less likely to aggressively pursue the filing or approval of ANDAs when faced with these added hurdles and complications, and the FDA has less resources available for legitimate scientific research when it is forced to respond to a series of extensive but baseless citizen petitions. Moreover, FDA has policies to prioritize or expedite review of ANDAs that otherwise have a clear path to market (as would have been the case for Restasis ANDAs as of May 2014 were it not for Allergan's sham patents and petitioning).

94. The Restasis ANDA filers that nonetheless waded into this Allergan-orchestrated morass had no choice but to contend with the resulting hurdles. As Mylan's CEO Heather M. Bresch stated in Mylan's November 3, 2017 earnings call, "I think this is a great example of [Mylan] persevering through what I would call [Allergan's] pretty desperate legal maneuvers to try to maintain a monopoly that should have been gone a couple of years ago, and our ability continue to fight not only in the courts, but with the science and have a clear pathway to approvals."

95. Had scientists, regulatory professionals, and lawyers at Mylan, other generic manufacturers, and the FDA not been tied up by Allergan's "desperate legal maneuvers," and had they not been forced for years to "continue to fight" Allergan's anticompetitive conduct, they would have remained focused solely on ensuring that safe and effective generic version(s) of Restasis were approved "years ago" at, or as near as possible to, the expiration of the '979

patent in May 2014. This delay in competition is exactly what Allergan intended to, and did, cause through its unlawful scheme.

E. Allergan Files Sham Patent Infringement Suits to Delay Generic Entry

96. In response to Allergan's Orange Book listings, and exactly as Allergan had planned, generic competitors provided paragraph IV certifications with respect to the second wave patents. Generic manufactures Apotex, Akorn, Mylan, and Teva all submitted paragraph IV certifications within weeks of each other starting in July 2015, asserting that the second wave patents either were invalid or non-infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate basis to enforce them. Yet Allergan responded to each of the above paragraph IV certifications from potential generic competitors by filing multiple patent infringement actions, beginning on August 24, 2015.

97. These infringement suits triggered the automatic 30-month stay of any FDA final approval of these ANDAs.

98. On October 16, 2017, after trial in August, the Texas federal court found the second wave patents invalid based on obviousness. In a thorough 135-page post-trial Findings of Fact and Conclusions of Law, the court found that Allergan had secured these Patents "by way of a presentation that was more advocacy than science." Invalidation Decision at 133. The court found particularly compelling the 2009 concessions, the fact that Allergan's "unexpected" results were foreseeable based on the early cyclosporine studies, and that in any event, the "new" Restasis formulation claimed by the second wave patents had statistically the same efficacy as one of the prior art examples in Ding I.

99. The court also dismissed other arguments Allergan made at trial, including assertions that the surprise results arose from a difference between the Phase 2 and 3 studies, and

that there were objective, valid reasons for issuing new patents:

> While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [second wave] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.[6]

100. Allergan brought these multiple infringement suits, regardless of any objective merit. Indeed, Allergan had conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the second wave patents) were obvious in light of Ding I, and Allergan knew it had obtained the second wave patents only through its fraudulent misrepresentations to the PTO. Accordingly, there never was any objective merit to any of these infringement suits. The objective merits were irrelevant, however, to Allergan's true purpose. Allergan filed those suits not to vindicate any legitimate patent infringement issues but to improperly use governmental process and the workings of the Hatch-Waxman act to delay generic competition to its Restasis monopoly.[7] If it filed even the most baseless of patent infringement suits, Allergan knew it would still obtain and immediately benefit from the automatic 30-month stay of FDA final approval of any generic Restasis product. For a $1.5 billion/year franchise, every extra month Allergan could postpone competition from generic

[6] *Id.* at 134-35. The Court noted that Allergan had success and met a need not because it was at the forefront of innovation in a competitive setting, but because it had enjoyed a long period of patent protection, which ensured that it would be the only party that would be able to invent and exploit a cyclosporine/castor oil product.

[7] Indeed, Allergan's subjective intent in filing these suits is evident from the complaint it filed. In its prayer for relief, Allergan demanded that the Texas federal court order, notwithstanding any lacking authority to do so, that "the effective date of any FDA approval" of any Restasis ANDA be "a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity" of the second wave patents. *See* ECF No. 96 at 127, 129, 131, 132.

Restasis added another $125 million to its revenues!

F. Allergan Abuses the FDA's Citizen Petition Process to Delay Generic Entry

101. Another prong of Allergan's multifaceted scheme was to delay the FDA's approval of any Restasis ANDA by hijacking the agency's citizen petition process (described above).

102. Allergan's citizen petitions related to FDA's June 2013 non-binding, draft guidance giving Restasis ANDA applicants two options to demonstrate the bioequivalence necessary to secure FDA ANDA approval. Pursuant to the June 2013 draft guidance, to establish the bioequivalence of generic Restasis with its branded counterpart, Restasis ANDA applicants could use one or both of: (1) in vivo testing (*i.e.*, testing performed on live humans, often referred to as "clinical endpoint studies"); or (2) in vitro testing (*i.e.*, a test tube). Generic drug makers typically use in vitro testing in their ANDAs to demonstrate bioequivalence with a branded drug, because it is cheaper and less time-consuming than the in vivo clinical trials that brand-name drug companies generally must undertake in support of their original NDA, studies which the FDA believes "may present economic and logistical challenges for ANDA sponsors."

103. Allergan gave the FDA its views on the draft guidance in a lengthy comment submitted to the agency in August 2013, asserting that the FDA could not approve any Restasis ANDA relying on in vitro testing and asking the FDA to "replace the Draft Guidance with a revised guidance document that explains in vivo comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to" Restasis. Allergan's criticism of the draft guidance was echoed by comments submitted by several doctors who, unbeknownst to the FDA, had in 2013 received payments of up to $70,000 from Allergan for "consulting" on Restasis. The FDA typically publishes its responses to the public comments received in response

to its draft guidance, but is not required (like it is with a citizen petition) to formally respond to individual requests to take (or refrain from taking) action.

104. Despite having aired its criticism of the FDA's draft guidance during the August 2013 comment period, Allergan nonetheless began inundating the FDA with citizen petitions immediately following its improper listing of the first second wave patent in the Orange Book in January 2014. While Allergan asserted that its citizen petitions were submitted to tell the FDA that "rushing prematurely to approve a proposed generic drug [not supported by in vivo clinical endpoint studies] poses a risk to patient health," Allergan's true goal was to delay the FDA's review of any Restasis ANDAs by saddling the agency with baseless, duplicative citizen petitions relating to the 2013 draft guidance – a tactic that Allergan told investors exemplified its response to "intense competition from generic drug manufacturers."

105. Allergan's first citizen petition was submitted to the FDA on January 15, 2014, and was superseded by another citizen petition filed on February 28, 2014 (the "February 2014 Citizen Petition," which largely parroted its public comments to the FDA in August 2013). Among the February 2014 Citizen Petition's six requests – each of which required a formal, time-consuming response from the FDA within 180 days – was to ask that the FDA "make clear that the only way to demonstrate bioequivalence to Restasis is through comparative clinical endpoint studies [*i.e.*, in vivo]," and "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence." The February 2014 Citizen Petition cited to the public comments submitted by its cadre of paid doctors, ostensibly "draw[ing] from their clinical experience, criticizing the draft guidance's in vitro approach."

106. The FDA largely rejected the requests in the February 2014 Citizen Petition, explaining in its November 20, 2014 response to Allergan that the in vitro-only option in its June 2013 draft guidance was consistent with "the Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data," which enabled the FDA "to effectuate several long-standing policies that protect the public health" when approving ANDAs for generic drugs.

107. The FDA then explained that with respect to "locally acting, non-systemically absorbed drug products" like Restasis, the in vivo studies urged by Allergan's citizen petition were "usually of limited utility," noting that while its 2013 draft guidance for Restasis ANDAs had recommended using either in vivo or in vitro studies, the "modest efficacy demonstrated by Restasis" meant that an in vivo bioequivalence study "may not be feasible or reliable." The November 20, 2014 letter then explicitly rejected Allergan's request that Restasis ANDAs based on in vitro bioequivalence studies be rejected, telling Allergan that the FDA concluded that "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic Restasis.

108. The FDA's rejection of the February 2014 Citizen Petition did not dissuade Allergan from its efforts to further delay generic competition for Restasis by abusing the citizen petition process, and the company submitted a second citizen petition on December 23, 2014 (the "December 2014 Citizen Petition"), which consisted largely of repetitions of the arguments in the February 2014 Citizen Petition. Allergan supplemented the December 2014 Citizen Petition four times, including an August 16, 2015 supplement in which Allergan requested (among other things) that the FDA convene a committee of outside experts to evaluate the use of in vitro

methods for generic Restasis, and that the FDA refuse to receive, review or approve any Restasis ANDAs until that outside evaluation was complete.

109. The FDA rejected the December 2014 Citizen Petition and its many supplements, stating in its February 10, 2016 response that the December 2014 Citizen Petition "repeat[ed] many of the assertions that were at the center of Allergan's previous petition," and declined to repeat the agency's detailed answers from its November 20, 2014 response to the February 2014 Citizen Petition.[8] The February 10, 2016 letter again expressed doubts about the in vivo studies that Allergan was urging be required for any Restasis ANDAs, and noted that the claims in the December 2014 Citizen Petition "lack legal support" and "rest on flawed logic." Despite the FDA's misgivings about the lack of sound, substantive bases for Allergan's citizen petitions, it was nonetheless obligated to specifically respond to each of Allergan's requests, and informed Allergan in its February 10, 2016 letter that it would "not approve or receive any ANDA referencing Restasis based on in vitro assays unless and until FDA responds specifically to the findings of Allergan's testing of nine experimental test emulsions" submitted with the December 2014 Citizen Petition. In other words, the FDA was delaying approving any Restasis ANDA because of Allergan's serial citizen petition campaign; Allergan's tactic had succeeded.

G. Allergan Enters a Sham Agreement with the Saint Regis Mohawk Tribe in a Naked Attempt to Avoid PTAB Invalidation of the second wave patents

110. Allergan's latest effort to forestall competition in the market for cyclosporine stems from a series of inter partes review (IPR) requests. In June 2015, Apotex, which subsequently provided Allergan notice of its second wave patent paragraph IV certifications on July 23, 2015, was the first ANDA applicant to petition the PTAB to initiate an IPR review of

[8] The FDA nominally granted two minor requests, but they did not change the FDA's practice. In the absence of Allergan's petitions the FDA would have taken those requested actions anyway.

the second wave patents. Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that the PTAB would invalidate the second wave patents. By that time, however, other ANDA applicants, including Mylan and Teva, had also petitioned the PTAB for IPR proceedings on the second wave patents. In December 2016, the PTAB resolved the same question that the Allergan settlement with Apotex mooted the year before, concluding that there was a reasonable likelihood that each of the second wave patents would be invalidated upon the PTAB's further review and thereby instituted proceedings against all six of the second wave patents.[9]

111. On September 8, Allergan entered into an ostensible agreement with the Tribe to convey ownership of the second wave patents to the Tribe with an exclusive license back to Allergan for "all FDA-approved uses in the United States" and a promise not to waive the Tribe's sovereign immunity with respect to any IPR or other administrative action in the PTO related to the Patents. The agreement provided for a payment to the Tribe of $13.75 million from Allergan, plus potentially $15 million in annual royalties. On September 22, after the Tribe and Allergan agreed to this sham transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity.

112. No objectively reasonable litigant could expect these shenanigans before PTAB to succeed. Multiple cases have rejected similar schemes to game the law, including in the context of sovereign tribes where the only interest the tribe had was in being paid for the cover of immunity. *See People* ex rel. *Owen v. Miami Nation Enterprises*, 386 P.3d 357 (Cal. 2016). The

[9] Because the terms of Allergan's settlement with Apotex in December 2015 (that avoided for as much as a year any risk that any of the second wave patents would be invalidated) were not made public, Plaintiffs are presently unable to determine the extent to which that settlement may have violated *FTC v. Actavis*, 133 S. Ct. 2223 (2013), and thus constitute yet another component in Allergan's overall scheme.

trial court in this district in the infringement case which Allergan recently lost agreed to join the Tribe as a co- plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. The court explained that despite its "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed," it would "adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented." *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455, ECF No. 522 at 4, 9 (E.D. Tex. Oct. 16, 2017).

113. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan's chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid "double jeopardy," that is, to intentionally disrupt adjudicative proceedings in one of the two venues, even though Allergan itself had initiated proceedings in the other and could voluntarily dismiss that other action at any time.

114. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry, and in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry.[10] Licensing the second wave patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had prior to September 2017, and, from the Tribe's comments, is not made pursuant to a natural future interest either. Nor was the Tribe acting in its sovereign capacity, *e.g.*, regulating the sale or use of cyclosporine on a reservation, in entering its agreement with Allergan.

[10] *See* Saint Regis Mohawk Tribe Office of Technology, Research and Patents, *Frequently Asked Questions About New Research and Technology (Patent) Business* at 1, https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.").

VI. CLASS ALLEGATIONS

115. FWK, on behalf of itself and all other similarly situated direct purchasers, seeks damages, measured as overcharges, trebled, against Allergan based on allegations of anticompetitive conduct in the market for Restatis and its AB-rated generic equivalents.

116. FWK brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as a representative of a Class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

> All persons who or entities which purchased Restasis in the United States or its territories and possessions directly from Allergan at any time after May 17, 2014 through and until the anticompetitive effects of Allergan's conduct cease (the "Class Period").
>
> Excluded from the Direct Purchaser Class are Allergan and its officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

117. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. FWK believes that the Class is composed of scores of entities. Further, the Direct Purchaser Class is readily identifiable from information and records in Allergan's possession.

118. FWK's claims are typical of the Direct Purchaser Class claims. FWK and all Class Members were damaged by the same wrongful conduct of Allergan, *i.e.*, they paid artificially inflated prices for cyclosporine and were deprived of earlier and more robust competition from less-expensive generic cyclosporine as a result of Allergan's wrongful conduct.

119. FWK will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the FWK are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

120. FWK is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving

pharmaceutical products.

121. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions that may affect only individual Class Members because Allergan has acted on grounds generally applicable to the entire Direct Purchaser Class thereby making overcharge damages with respect to the Direct Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in Allergan's wrongful conduct.

122. Questions of law and fact common to the Direct Purchaser Class include:

i. Whether Allergan willfully obtained and/or maintained monopoly power over Restasis and its generic equivalents;

ii. Whether Allergan obtained the second wave patents by fraud;

iii. Whether Allergan unlawfully excluded competitors from the market for Restasis and its AB-rated generic equivalents;

iv. Whether Allergan unlawfully delayed or prevented generic manufacturers of cyclosporine ophthalmic emulsion from entering the market in the United States;

v. Whether Allergan maintained monopoly power;

vi. Whether Allergan's agreement with the Tribe violated Section 1 of the Sherman Act;

vii. Whether there was any legitimate business justification for the anti-competitive contract between Allergan and the Tribe, and whether the anti-competitive effects of that contract outweigh any reasonable pro-competitive benefits or justifications;

viii. Whether Allergan and the Tribe conspired to monopolize the Restasis

market;

ix. Whether the law requires definition of relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

x. Whether Allergan's activities as alleged herein have substantially affected interstate commerce;

xi. Whether, and if so to what extent, Allergan's conduct caused antitrust injury (*i.e.*, overcharges) to FWK and Class Members; and

xii. The quantum of aggregate overcharge damages to the Class.

123. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

124. FWK knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND DEFINITION

125. The relevant geographic market is the United States and its territories and possessions.

126. At all relevant times, Allergan's share of the relevant cyclosporine ophthalmic emulsion market was and remains 100%.

127. At all relevant times, Allergan had monopoly power in the market for Restasis

and its AB-rated generic equivalents because it had the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Restasis, with the exception of AB-rated generic cyclosporine ophthalmic emulsion products. This market power may be shown directly, and therefore no relevant market needs to be defined.

128. Allergan has enjoyed monopoly power conferred by the Ding I patent since 1995, and since 2003, when it launched Restasis pursuant to FDA approval, Allergan has reaped significant commercial benefits. When it received FDA approval in December 2002, Allergan represented Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In its numerous filings with the FDA, Allergan has similarly represented Restasis' uniqueness: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." Allergan, Inc., Citizen Petition, Feb. 28, 2014, at 13.

129. Manufacturers attempt to differentiate brand name drugs like Restasis based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Restasis. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Restasis.

130. Other products are not practical substitutes for cyclosporine. Artificial tears offer only ephemeral relief and do nothing to address the underlying causes of dry eye. Corticosteroids can address the inflammation associated with dry eye, but have unwanted side effects, as do devices like "punctal plugs," which block the tear ducts and help the eye retain naturally produced tears for longer. Patients treated with cyclosporine would not switch to these products in response to a small but significant non-transitory increase in the price of cyclosporine in sufficient numbers to make such a price increase by a hypothetical monopolist unprofitable. Shire US, Inc.'s introduction last year of its rival DED product, Xiidra, has not resulted in lower Restasis prices, thus confirming Allergan's continued market power over the relevant cyclosporine market.[11]

131. Allergan's ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates lack of substitutability between Restasis and other drug products.[12] Restasis does not exhibit significant, positive cross-elasticity of demand with respect to price with any other DED medication. Other various DED treatments may exist, but none exhibit cross price elasticity with and therefore do not constrain the price of Restasis. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives, to the extent existent, are not the same as economic alternatives.

[11] It may be that Allergan is also improperly using its monopoly power in the cyclosporine market to unlawfully restrain Xiidra sales. In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an "ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan." Compl., *Shire US, Inc. v. Allergan, Inc. et al.*, No. 2:17-cv-07716 (D.N.J. Oct. 2, 2017).

[12] *See* David Crow, *Allergan Deal with Mohawk Tribe Casts Patent Shadow*, *Fin. Times*, Sept. 27, 2017 ("The average wholesale price of a 30-dose pack of Restasis has more than doubled from $117 in 2008 to almost $280 today").

132. Functional similarities between Restasis and other DED medications, other than AB-rated generic Restasis equivalents are insufficient to permit inclusion of those other molecules in the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. No other DED medication (except for AB-rated generic versions of Restasis) will take way sufficient sales of Restasis to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

133. Restasis is also not reasonably interchangeable with any products other than AB-rated generic versions of Restasis because Restasis has significantly differentiating attributes making it a unique drug product. The FDA does not consider Restasis interchangeable with any other medication. Nor does Allergan. For example, Restasis is a topical ophthalmic formulation, and as Allergan has explained, "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

134. Allergan needed to control only Restasis and its AB-rated generic equivalents, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to maintain its monopoly prices of Restasis without losing substantial sales.

135. Allergan also sold Restasis at prices well in excess of marginal costs, and

substantially in excess of the competitive price, and enjoyed high profit margins.

136. Allergan has exercised its power to exclude and restrict competition to Restasis and its AB-rated equivalents.

137. Allergan, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of cyclosporine ophthalmic emulsion due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and high costs of entry and expansion.

138. To the extent FWK is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, FWK alleges that the relevant market is all cyclosporine ophthalmic emulsion products (*i.e.*, Restasis in all its dosage strengths, and its AB-rated generic equivalents). During the period relevant to this case, Allergan has been able to profitably maintain the price of cyclosporine ophthalmic emulsion products well above competitive levels.

VIII. MARKET EFFECTS AND CLASS DAMAGES

139. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic cyclosporine ophthalmic emulsion products starting as early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its monopoly power in the market for cyclosporine ophthalmic emulsion through a scheme to exclude competition. The scheme forestalled generic competition and carried out its anticompetitive effect of maintaining supracompetitive prices for Restasis. Allergan implemented its scheme by fraudulently obtaining the second wave patents, wrongfully listing these knowingly invalid patents in the Orange Book, prosecuting sham patent infringement lawsuits against the generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and

entering into an anti-competitive agreement with the Tribe in a blatant attempt to insulate the second wave patents from invalidation in the PTAB IPR proceedings. These acts, individually and in combination, were anticompetitive.

140. If Allergan had not defrauded the PTO, (i) the second wave patents would never have been issued, (ii) Allergan could never have used those second wave patents as a vehicle to bring sham suits, predicated on knowingly invalid patents, against would-be makers of generic cyclosporine ophthalmic emulsion products, the filing of which automatically stayed any FDA final approvals of all would-be generic alternatives, and (iii) AB-rated generic Restasis manufacturers would have been able to launch generic cyclosporine ophthalmic emulsion products by May 17, 2014.

141. Allergan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis from generic competition. Allergan's actions allowed it to maintain a monopoly and exclude competition in the market for cyclosporine ophthalmic emulsion, *i.e.*, Restasis and its AB-rated generic equivalents.

142. Allergan's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Restasis without generic competition. But for the illegal conduct of Allergan, one or more of the following ANDA-filers would have begun marking generic versions of Restasis at least as early as May 17, 2014.

143. The generic manufacturers seeking to sell generic Restasis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand, and at least several of these generic manufacturers would have

been ready, willing, and able to launch its generic version of Restasis as early as May 17, 2014 were it not for Allergan's unlawful acts.

144. Allergan's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any generic version of Restasis, has caused and will cause FWK and the Class to pay more than they would have paid for cyclosporine ophthalmic emulsion, absent Allergan's unlawful conduct.

145. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart as to which they are AB-rated. As a result, upon generic entry, direct purchasers' purchases of brand drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generic versions of the drug.

146. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

147. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Allergan, direct purchasers, such as FWK and members of the Class, would have paid less for cyclosporine ophthalmic emulsion by (a) substituting purchases of less expensive AB-rated generic Restasis for their purchases of more-expensive branded Restasis, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c)

purchasing Restasis at lower prices sooner.

148. Thus, the unlawful conduct of Allergan deprived FWK and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

149. During the relevant period, FWK and members of the Class purchased substantial amounts of Restasis directly from Allergan. As a result of Allergan's unlawful anticompetitive conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were substantially greater than the prices that Plaintiffs and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Restasis was artificially inflated by Allergan's illegal conduct, and (2) Class Members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

150. As a consequence, FWK and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. COUNT ONE

VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. §2: MONOPOLIZATION THROUGH *WALKER PROCESS* FRAUD

151. FWK repeats and incorporates by reference all preceding paragraphs and allegation.

152. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no

other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

153. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by wrongfully asserting patents obtained by fraud to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

154. Allergan knowingly and intentionally asserted the invalid second wave patents in order to maintain its monopoly power. This was intended to, and in fact had the effect of, blocking and delaying entry of AB-rated generic versions of Restasis.

155. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar), made misrepresentations of fact to the Patent and Trademark Office. These included:

- Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Teat Test score in the first study of Allergan's Phase 3 trials compares to the relative efficacy for the … formulation discussed in Example 1E of Ding, tested in Phase 2 trials…. This was clearly a very surprising and unexpected result."

- Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "…the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staningin score in both of the Phase 3 studies compared to the … formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result."

- Figures 1-4 in Dr. Schiffman's declaration reported figured from the Sall paper but omitted all error bars and p-values. In truth, as the Court later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values

for the pair-wise comparisons were very high.[13] The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance.

- Dr. Schiffman did not disclose to the PTO that he was comparing different Schirmer tear test scores – one without anesthesia in Phase 2 and one with anesthesia in Phase 3 – in order to purportedly show a difference in efficacy. As the Court later found, only the Schirmer tear test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation. "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation' was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper.

- Dr. Schiffman did not disclose to the PTO that the method he chose to calculate the differences in efficacy "exaggerated the difference in the raw values between the two."[14]

- The calculations in Dr. Schiffman's table are misleading:

    a. Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results

    b. Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant.

    c. Dr. Schiffman only included data from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the second wave formulation.

- Dr. Schiffman did not tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was "unexpected" as of the Restasis patent's priority date.

156. These representations were material. The examiner had repeatedly rejected the applications as obvious before Allergan's misleading statements and omissions. The examiner had also earlier rebuffed Allergan's purported secondary considerations of non-obviousness

[13] *Id.* at 76.

[14] *Id.* at 78.

(including commercial success and unmet need). The PTAB's later decision, as well as this Court's later decision, support the materiality of these misrepresentations and omissions.

157. Allergan made these statements with intent to deceive the PTO. The misleading statements were made intentionally, not accidentally. Allergan was motivated to obtain a longer period of patent protection, given the large sales of Restasis and the importance of the product to the company. The misleading statements were only made after the examiner rejected the application (not with the initial filing) and were made to overcome a rejection and support patentability. There is no innocent explanation for presenting the information as it was presented in the misleading declaration and accompanying submissions; the only reasonable inference is that Allergan intended to deceive the PTO.

158. The PTO reasonably relied on Allergan's false and misleading statements in issuing the second wave patents. The examiner stated that the Schiffman declaration was deemed sufficient to overcome his earlier rejection based on Ding I because "Examiner is persuaded that, unexpectedly, the claimed formulation … demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I." The Examiner also explained that the declarations "illustrate that the claimed formulations … also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compare to the … formulation tested in Phase 2 and disclosed in Ding…."

159. But for Allergan's misrepresentations and omissions, the second wave patents would not have issued. Had they not issued, there was no patent-based impediment to generic versions of Restasis entering the market from May 17, 2014 onwards.

160. Allergan listed the second wave patents in the Orange Book and later asserted them against all would-be generic competitors.

161. But for Allergan's asserting the fraudulently obtained patent, generic versions of Restasis would have been available as early as May 17, 2014, and in any case within the Class Period.

162. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

XI. COUNT TWO

VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. §2: MONOPOLIZATION THROUGH OVERARCHING ANTICOMPETITIVE SCHEME

163. FWK repeats and incorporates by reference all preceding paragraphs and allegations.

164. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

165. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

166. Allergan knowingly and intentionally engaged in an anticompetitive scheme in order to maintain its monopoly power, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Restasis. This scheme included:

- Prosecuting serial baseless patent applications and ultimately obtaining the second wave patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;
- Improperly listing the second wave patents in the Orange Book;
- Engaging in multiple sham litigations;
- Submitting serial sham citizen petitions; and
- Abusing the Patent Trial and Appeal Board's *inter partes* review process through sham transfer of the second wave patents to the Saint Regis Mohawk Tribe.

167. By means of this scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to Restasis in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, FWK and members of the Class paid artificially inflated prices for their cyclosporine ophthalmic emulsion requirements.

168. FWK and members of the Class have been injured in their business or property by Allergan's antitrust violations. Their injury consists of having paid higher prices for their cyclosporine ophthalmic emulsion requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Allergan's conduct unlawful, and FWK and the Class are the proper entities to bring a case concerning this conduct.

169. Allergan knowingly and intentionally committed Walker Process fraud to induce the PTO to grant the second wave patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted false sworn

declarations in 2013, that Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by prior art (*i.e.*, Ding I), when in fact the data presented was neither new or surprising. Had Allergan made clear to the PTO examiner that the 2013 declarations statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan's Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the second wave patents.

170. Allergan knew when it listed the second wave patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the second wave patents should not have been listed in the Orange Book. Allergan knew that listing the second wave patents in the Orange Book would force ANDA applicants to file paragraph IV certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, could trigger an automatic stay of any FDA final approval of any new paragraph IV-certified ANDA applicant's generic Restasis product for a period of up to 30 months.

171. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis. Allergan intentionally and deceptively alleged the generic manufacturers' products infringed its second wave patents, knowing when those suits were filed that such patents were wrongfully obtained though fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the

related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently-obtained and otherwise invalid second wave patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed this sham lawsuit for the purposes of using a governmental process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly power over Restasis, regardless of any actual merit to its infringement claims.

172. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA the purpose and intent to which was delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition.

173. Allergan knowingly and intentionally transferred the second wave patents to the Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands located in New York—in an attempt to evade invalidation of those patents and cessation of its Restasis monopoly, which illustrates the extraordinary measures Allergan was willing to take in its stop-at-nothing desperation to delay competition.

174. Allergan's anticompetitive conduct as alleged herein is not entitled to any qualified Noerr-Pennington immunity, nor is it protected by the state action doctrine.

175. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not

cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

XII. COUNT THREE

VIOLATION OF SECTION ONE OF THE SHERMAN ACT, 15 U.S.C. § 1: CONTRACT IN RESTRAINT OF TRADE

176. FWK repeats and incorporates by reference paragraphs 1 through 46.

177. Defendant entered into a contract, with the Tribe in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

178. Defendant's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the United States Restasis market, and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for Restasis and raising and maintaining Restasis prices at supra-competitive levels throughout the United States.

179. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the Restasis market, and both Allergan and the Tribe have profited from their illegal contract by maintaining prices at artificially high levels.

180. There is no legitimate business justification for the anti-competitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market, including the contract between Allergan and the Tribe. The anti-competitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

181. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiffs and member of the Class have been and continue to be injured by their business or property.

182. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiff and the other members of the Class have been forced to pay artificially high, supra-competitive prices for Restasis and were harmed thereby.

183. Plaintiff and members of the Class are entitled to treble damages to remedy the injuries they have suffered from Allergan's and the Tribe's violations of Sherman Act § 1, 15 U.S.C. § 1.

XIII. COUNT FOUR

VIOLATION OF SECTION TWO OF THE SHERMAN ACT, 15 U.S.C. §2: CONSPIRACY TO MONOPOLIZE

184. FWK repeats and incorporates by reference all paragraphs 1 through 46.

185. Allergan and the Tribe have conspired to allow Allergan to willfully maintain and unlawfully exercise monopoly power in the Restasis market through the anti-competitive contract with the specific intent to monopolize the Restasis market, and preventing competition in the market.

186. As a result of the conspiracy, Allergan and the Tribe have effectively excluded competition from the Restasis market, unlawfully maintained Allergan's monopoly in the Restasis market, and profited from their anti-competitive conduct by maintaining prices at artificially high levels.

187. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the Restasis market, including the contract between Allergan and the Tribe. The anti-competitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

188. There is no legitimate business justification for the anti-competitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market. The anti-competitive effects of Allergan's and the Tribe's agreement far outweigh any conceivable pro-competitive benefit or justification.

189. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiffs and member of the Class have been and continue to be injured by their business or property.

190. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiff and the other members of the Class have been forced to pay artificially high, supra-competitive prices for Restasis and were harmed thereby.

191. Plaintiff and members of the Class are entitled to treble damages to remedy the injuries they have suffered from Allergan's and the Tribe's violations of Sherman Act § 2, 15 U.S.C. § 2.

XIV. PRAYER FOR RELIEF

WHEREFORE, FWK, on behalf of itself and the Class, prays that the Court:

i. Determine that this action may be maintained as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare FWK as a named representative of the Class;

ii. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

iii. Enter judgment against Allergan and in favor of FWK and the Class;

iv. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

v. Award FWK and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

vi. Award such further and additional relief as is necessary to correct for the

anticompetitive market effects caused by Allergan's unlawful conduct, as the Court may deem just and proper under the circumstances.

XV. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, FWK, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: November 17, 2017	Respectfully submitted, /s/ S. Calvin Capshaw
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